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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,162	08/26/2003	Raymond E. Ideker	5656-33	3541
7590 08/23/2007				
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			EXAMINER	
			BERTRAM, ERIC D	
			ART UNIT	PAPER NUMBER
			3766	
			MAIL DATE	DELIVERY MODE
			08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/648,162	Applicant(s) IDEKER, RAYMOND E.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15-18, 21-49 and 52-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-18, 21-49 and 52-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's arguments with respect to claims 1-12, 15-18, 21-49 and 52-57 have been considered but are moot in view of the new ground(s) of rejection, necessitated by applicant's amendment.
2. Furthermore, the applicant is reminded that, as described in the previous Office Action, upon reviewing the specification, the applicant merely describes chronic detection as detection "over an extended duration of time," and that the detection need not be continuous (page 3, lines 30-35). Therefore, since "chronically" is a relative term, and no actual time scales are supplied by the applicant to appropriately define "chronically" or "an extended period of time," any detection that occurs more than once shall be considered "chronic detection."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-3, 5-12, 15-18, 21-26, 28-40, 42-49 and 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konta et al. (*Significance of Discordant ST Alternans in Ventricular Fibrillation*, hereinafter Konta) in view of Christini et al. (US 6,915,156, hereinafter Christini). Konta discloses a method and system for detecting discordant alternans in a subject wherein 60 silver electrodes are implanted at distinct locations on the exposed pericardium of a patient in order to allow for the *chronic* detection of electrograms over a 7 minute occlusion period using a data processing system (page 2185, Col. 2). In order to identify the discordant alternans, the voltages of the ST segments from adjacent leads were compared to determine of the alternans where in phase (concordant) or out of phase (discordant) (page 2186, Col. 1, par. 2). However, Konta does not specifically disclose initiating interventional therapy in response to the identification of discordant alternans. Regardless, Konta discusses that discordant alternans are related to the development of ventricular fibrillation, which is a life-threatening condition requiring immediate treatment in a patient (page 2187, Col. 1). Furthermore, Konta does state that discordant alternans can be suppressed by treatment with the drug verapamil (page 2188, Col. 1). Therefore, despite the fact that Konta does not distinctly teach initiating therapy following detection of discordant alternans, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to deliver the drug verapamil to a patient following detection of discordant alternans in order to prevent or treat the occurrence of ventricular fibrillation, as is suggested by Konta.

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6. Despite utilizing implanted electrodes, Konta does not disclose using electrodes that are positioned in an internal chamber and/or vessel of the heart of the subject.

Attention is directed to the secondary reference of Christini, which discloses implanting electrodes attached to leads (i.e., catheters) in the heart of the patient in order to detect electrical activity of the heart and identify alternans (see title, abstract and col. 2, lines 54-58). Therefore, since both Konta and Christini disclose methods for chronically detecting electrical activity in the heart and then identifying alternans, it would have been obvious to one of ordinary skill in the art at the time of the applicant's to substitute one method for the other to achieve the duplicate, equal and predictable result of detecting electrical activity of the heart to identify alternans.

7. Regarding claim 33, Konta further discloses an external electrode for recording surface electrograms, demonstrating that the use of external electrodes to monitor cardiac electrograms is notoriously old and well known in the art.

8. Regarding claims 10, 11, 22-24, 47 and 48, Konta, as described above, discloses the applicant's basic invention with the exception of applying electrical stimuli to the heart in order to provide therapy to a patient in response to the detection of discordant alternans. Attention is directed to the secondary reference of Christini, which discloses applying electrical stimuli to a patient in order to control and stabilize discordant alternans in a patient (Col. 6, lines 53-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system/method of Konta by applying electrical stimuli to a patient since this is a known technique for stabilizing discordant alternans, as taught by Christini.

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9. Claims 4, 27 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konta and Christini in view of Pastore et al. (US 6,965,797, hereinafter Pastore). Konta, as described and modified above, discloses the applicant's basic invention with the exception of using alternations in an activation recovery interval (ARI) to identify discordant alternans. Attention is directed to the secondary reference of Pastore, which teaches that the activation recovery interval of heart tissue may be used to identify pulse alternans, of which discordant alternans may be included. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method and system of Konta, as modified, by using ARI to identify discordant alternans since this is a known method of determining the existence of alternans in the heart.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766


Mark Bockelman
Primary Examiner
Art Unit 3766

EDB